REMARKS

Introductory Comments

Reconsideration of the above-identified application in view of the above amendments and foregoing arguments is respectfully requested.

Claims 17-19 are pending and are under consideration. The specification and claim 17 have been amended. The specification has been amended to correct a typographical error and to update the priority data. No new matter has been added as a result of these amendments.

Objection to the Preliminary Amendment

The preliminary amendment dated November 26, 2001 was objected to because Applicants requested cancellation of claims from the parent application. Applicants erred in making the request and withdraw from the request. Accordingly, Applicants respectfully request withdrawal of the objection.

Rejection of Claim 17 Under 35 U.S.C. § 101

Claim 17 is rejected under 35 U.S.C. § 101 because the claim is directed to non-statutory subject matter. Specifically, the Examiner asserts that the claimed polypeptide occurs in nature and suggests amending the claim to recite "an isolated polypeptide."

Applicants thank the Examiner for the suggestion and have amended claim 17 to recite "an isolated polypeptide." Accordingly, Applicants respectfully request withdrawal of the rejection of claim 17 under 35 U.S.C. § 101.

Rejection of Claims 17-19 Under 35 U.S.C. § 101

Claims 17-19 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific, substantial asserted utility or a well established utility. Specifically, the Examiner asserts that while the specification

discloses utilities for the full length polypeptide of SEQ ID NO: 27 and fragments thereof comprising SEQ ID NO: 28-31, including diagnosis, treatment of prostate tissue diseases, drug screening, production of screening of agonists, antibodies and antagonists, the specification and the art of record do not teach what SEQ ID NO: 27 is and what it does. The Examiner also states that they do not teach a utility for any of the fragments as claimed and do not teach a relationship to any specific disease nor establish any involvement in the etiology of any specific disease.

Applicants assert that the specification discloses and teaches what SEQ ID NO: 27 is and what it does. On page 6, the specification discloses a polypeptide encoded by PS118 having the sequence of SEQ ID NO: 27 and fragments thereof. At least one epitope is derived from SEQ ID NO: 27 and fragments thereof. The epitope allows an antibody to specifically bind to at least one PS118 epitope. Assay kits containing such polypeptides are used to determine the presence of PS118 antigen or anti-PS118 antibody in a test sample. On page 7, the specification discloses how these polypeptides may be produced, such as by incubating host cells transfected with an expression vector. Applicants would like to point out that what is disclosed on page 7 is a method of replicating copies of the polypeptide. It is not the only method of using the polypeptide as the Examiner alleges in the latter part of the Office Action. This is further discussed below. Thus, the specification discloses and teaches what SEQ ID NO: 27 is and what it does.

There are many examples of utility for SEQ ID NO: 27 and its fragments as recognized by the Examiner. The specification teaches a relationship to specific diseases and establishes the involvement in the etiology of specific diseases, in this case, prostate diseases. On page 3, the specification discloses that there is a need for finding a prostate-associated marker which is more sensitive in detecting the recurrence of prostate cancer than PSA and which is not affected by androgens. Examples of specific beneficial methods are also disclosed on page 7 and reiterated above. Such methods include assaying a test

sample for products of a gene which are overexpressed in prostate diseases. PS118 is such a gene linked to prostate tissue for overexpressed products.

Example 1 on page 54 of the specification describes how the consensus sequence was found greater than 12 times more in prostate than non-prostate tissues. Therefore, the specification teaches a relationship to specific diseases and establish the involvement in the etiology of specific diseases, in this case, SEQ ID NO: 27 which is derived from the PS118 gene in prostate diseases.

Furthermore, Applicants assert that the claims are drawn toward a product instead of a specific method of using the product. The utility requirement of 35 U.S.C. § 101 is met by Applicants' disclosure with respect to the product as claimed, the isolated polypeptide comprising of SEQ ID NO: 27 and its fragments, and is further discussed below.

The Examiner states that the use of the claimed sequences for the production of and screening of agonists, antibodies and antagonists applies to many unrelated polypeptide structure sequences. Therefore, the asserted utilities are not considered "specific." Applicants traverse the rejection based on this reasoning.

Just because the product can be used in a variety of methods does not take the product outside the fulfillment of the utility requirement of 35 U.S.C. § 101. The Examiner's reasoning would make a product which has many well-defined utilities non-statutory under 35 U.S.C. § 101. For example, just because a wheel has many uses, such as for transportation in a train, for movement in a toy, for steering a car in the steering wheel, or for different gears in a motor, such a variety of uses does not make it non-statutory. Applicants' product claims have "specific" utilities as further explained below.

On pages 4-5 of the Office Action, the Examiner states that although the specification discloses, in Example 1 and on page 54, Western blots showing two bands which are over-expressed in prostate cancer and benign prostate hyperplasia, the specification fails to provide control data concerning expression in normal prostate tissue. Because of this, the Examiner concludes that the

claimed sequences would not be suitable as markers for prostate diseases. Applicants respectfully traverse the rejection based on this reasoning.

Although the specification indicates that the disclosed sequences may be used in several ways, the Examiner has focused on the single utility of natural expression of the sequences in the cells themselves. Although Applicants will address the Examiner's contention relating to this specific utility, Applicants would like to point out that the claims are not drawn to a method of natural expression of the sequences in the cells themselves.

35 U.S.C. § 101 only requires one specific utility. For example, a claimed novel wheel that is square which has no known function for on-land or in-the-air vehicles but functions underwater, would have a specific utility as required under 35 U.S.C. § 101.

Applicants assert that there is more than one specific utility for the claimed polypeptide. First, a gene such as PS118 that is only expressed in the prostate cells is much more specific than a gene that is expressed in every cell in the body. The specification clearly states the importance of epitopes and complexes in the quest for finding markers of diseased tissues. The claimed polypeptide is at least useful for producing novel polypeptides that do not exist in nature, such as partial polypeptides, which may be useful as reagents in detecting diseases of the prostate. This, at least, is one specific utility of the claimed polypeptide. The argument that the claimed polypeptide which relates to a specific prostate gene does not have a single specific utility is unwarranted.

The following passages from the specification will make it clear as to Applicants' contention.

On page 12, lines 13-20 and page 13, line 24 to page 14, line 4, it is disclosed that immunological identity may be determined by antibody binding and/or competition binding as well known to those of ordinary skill in the art. Uniqueness of an epitope can be determined by a computer and is well known to those of ordinary skill in the art. On page 17, lines 5-11, it is disclosed the significance of an epitope, which is defined as an antigenic determinant of a polypeptide or a protein, and the method of determining such is by spatial

confirmation (x-ray crystallography or two dimensional nuclear magnetic resonance) which are known to those of ordinary skill in the art.

On page 13, line 24 to page 14, line 4, it is disclosed the significance of immunoreactivity which defines antibody recognition via a specific epitope, which determines antibody binding, competition and kinetics, all known to one of ordinary skill in the art. The significance of the use of reagents in indirect assays is stated on page 19, lines 7-19, page 19, line 33 to page 20, line 10 and page 20, line 14 to page 21, line 10.

As discussed in the specification beginning on page 3, there is a need in the art for the identification of new markers that can be used in the management of patients suffering from prostate disease. More specifically, such markers could be used to monitor for the elevated expression of such markers in inappropriate body compartments (i.e., outside of their normal host tissue, the prostate (See, specification, page 2, lines 3 to page 3, line 3.). The identification of such expression outside the normal host tissue would indicate prostate disease. An example of a well-known marker that is used in a similar manner is prostate specific antigen (PSA). PSA is normally secreted at high levels into the seminal fluid and is present in very low levels in the blood of men with normal prostates. However, in patients with diseases of the prostate, including benign prostatic hyperplasia (BPH) or adenocarcinoma of the prostate, the level of PSA is markedly elevated in the blood and is a strong indication of disease of the prostate.

Although PSA is the most important tumor marker for prostate cancer it is found in hyperplastic, primary and metastatic tissue (See Daniel W. Chan, et al., *JIFCC*, 9(3):120-125, 122 (1997)). More specifically, PSA has been found in male and female periurethral glands, anal glands, apocrine sweat glands, apocrine breast cancers, salivary gland neoplasms, and in human breast milk. *Id.* at 121. However, despite the fact that PSA is found in a variety of other tissue and cancer types, it is known in the art that serum concentrations of PSA correlate with prostate cancer tumor volume as well as clinical and pathologic

staging, with higher concentrations associated with advanced stages of prostate cancer. *Id.*

Tissue-specific markers, such as PS118, are also useful for identifying the origin of metastatic malignancies of unknown origin. The art recognized the importance of this use of tissue-specific markers (for use in the identification of the origin of metastatic malignancies of unknown origin) as early as 1992. For example, in an article by Bitran et al. entitled "Malignancies of Undetermined Primary Origin," in *Disease-A-Month,* 38:213-260 (1992), the authors state on page 221 that "[T]he patient who presents with metastatic malignancy of unknown primary origin, referred to hereafter as an unknown primary malignancy (UPM), is a clinical dilemma that is infrequently encountered yet is formidable and frustrating. Approximately 3% to 4% of cancer patients in general, and as many as 10% to 15% of patients with solid tumors, have metastases and no apparent primary tumor." Additionally, Bitran et al., go on to state that "[C]learly, improved diagnostic techniques in the future will yield information regarding the primary site of origin in what we now diagnose as UPM." *Id.* According to Bitran et al., patients with UPM typically have a limited life expectancy. In fact, at the time Bitran et al. was published, the median time period of survival for these patients was 3 to 7 months. *Id.* at 227.

The formidable and frustrating problem of metastic malignancies of unknown primary origin has been recognized by others skilled in the art, such as by MRCPath et al., in an article in *Anatomic Pathology*, 99(6):729-735 (June 1993)entitled "A Comparison of the Relative Contributions of Morphology, Minimal Essential Clinical Data and CEA Immunostaining Status" and Gamble et al., in *BMJ*, 306:295-298 (1993) in an article entitled "Use of tumour marker immunoreactivity to identify primary site of metastic cancer." In their article, MRCPath et al. state that despite meticulous searching, only a minority of patients that suffer from malignancies in which the primary site of origin is unknown are ever fortunate enough to have the primary site of their malignancy identified. Such searching usually involves subjecting the patient to extensive clinical, radiologic and surgical investigations that are painful and costly.

Unfortunately, the primary site of the malignancy is usually only discovered after the patient's death, during an autopsy. MRCPath et al. note that the identification of the primary site of such malignancies will become more crucial as treatment regimens become more individualized. In fact, MRCPAth et al. state that "[I]ncreasingly, pathologists are being asked to specify the likely primary site in cases of adenocarcinoma of an unknown primary site. As protocols including chemotherapy, radiotherapy, and immunotherapy become more specific, this trend will increase." *Id.* at 733.

MRCPath et al. recognized that individual immunohistologic tumor markers could have a role in helping to identify the site of origin of metastases in patients suffering from metastic malignancies of unknown primary origin. Specifically, MRCPath et al. noted that although "[T]hese markers might lack absolute site-specificity, but might prove useful as part of a panel." *Id.* at 729-730 (emphasis added).

Gamble et al. state that some patients suffering from metastic malignancies of unknown primary origin have responsive tumors that might respond to systemic treatment. Gamble et al. believe that "[A]ny diagnostic system that is quicker and cheaper than the present system would be of use". *Id.* at 295. In their study, Gamble et al. concluded that the "use of tumour markers in patients presenting with metastatic adenocarcinoma of unknown origin can help localize the probably primary sites and reduce the need for extensive and expensive imaging techniques." *Id.*

Applicants wish to remind the Office that according to the *Manual of Patent Examining Procedure* Section 2107.01 (8th Edition, February 2003 Revision) that "[A]ny reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit should be accepted as sufficient, at least with regard to defining a 'substantial' utility." Clearly, Applicants have identified a number of public benefits provided by the claimed invention.

On page 6, the Examiner further states that even if the claimed sequences are over-expressed, over-expression in a specific organ does not confer specific

utility. Applicants' claimed polypeptide has at least one specific utility as stated above. Applicants' response is incorporated herein.

Furthermore, the Examiner states that it is unlikely that SEQ ID NO: 27 or the encoding polynucleotides thereof is responsible for prostate cancer cell growth, because overexpression in prostate cancer as compared to other tissues does not necessarily confer any growth regulation property of prostate cancer cells. The Examiner concludes that since there is no correlation between overexpression of SEQ ID NO: 27 in prostate cancer as compared to other tissues, and because of the unpredictability of cancer treatment and gene therapy, it is unlikely that SEQ ID NO: 27 could be used for treating prostate tissue diseases.

Applicants have addressed the issue of overexpression and correlation to prostate diseases as state above. Therefore, Applicants' response is incorporated herein. With respect to the Examiner reasoning regarding the unpredictability of cancer treatment and gene therapy, the Examiner cites several articles indicating the failure of thousands of potential anticancer agents. The Examiner further expounded upon the problems of effective cancer treatment and the unpredictability of gene therapy (Pages 6-9 of the Office Action). As stated above, the claimed polypeptides have many utilities. Any difficulty incubating host cells transfected with an expression vector does not render the other disclosed utilities invalid. Host transfection with an expression vector is used for replicating polypeptides, instead of for diagnostic assays. Additionally, the failure of thousands of potential anticancer agents does not render the disclosed anticancer agents ineffective. Applicants' polypeptides are different from other anticancer agents because they are derived from a specified gene. Thus, the Examiner's comparison of Applicants' disclosed polypeptides to other unpredictable cancer treatment and gene therapy is unwarranted.

On page 9 of the Office Action, the Examiner alleges that neither the toxic substance nor the susceptible organ systems are identified from drug screening using the claimed probes. It appears that the Examiner is arguing that since SEQ ID NOS: 27-31 are applicable to a large class of drugs and proteins for

screening, that this is not considered a specific and well-established utility. The Examiner further alleges that since any potential utility is not yet known and has not yet been disclosed, the utility is not substantial because it is not currently available in practical form. The Examiner concludes by stating that one of ordinary skill in the art would require further experimentation which would mean that there is not a substantial utility.

As to the issue of the applicability of Applicants' claimed polypeptide to a large class of drugs and proteins for screening, this characteristic of the claimed polypeptide does not render the claims non-statutory under U.S.C. § 101. As stated above, comparisons such as these do not invalidate any of the polypeptide's other specific utilities. The use of aspirin for many purposes, such as a treatment for headaches to a treatment for heart disease, does not negate the aspirin's utility under 35 U.S.C. § 101.

To properly reject a claimed invention under 35 U.S.C. Section 101, the Examiner must (a) make a *prima facie* showing that the claimed invention lacks utility, and (b) provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* showing (*Manual of Patent Examining Procedure* Section 2107.02 (8th Edition, August 2001)). The Examiner must do more than question the operability of the invention. Specifically, the Examiner must set forth factual reasons that would lead one skilled in the art to question the objective truth of the statement of operability. *Id.*

In view of the above arguments and the evidence presented in previous amendments, Applicants respectfully submit that the Examiner has failed to make a *prima facie* showing that the claimed invention lacks utility. However, even assuming *arguendo* that the Examiner has made a *prima facie* showing that the claimed invention lacks utility, the Examiner has failed to provide a sufficient evidentiary basis for her factual assumptions relied upon in making this showing.

35 U.S.C. Section 101 has two purposes. First, 35 U.S.C. Section 101 defines the categories of inventions that are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented. Second, 35 U.S.C. Section 101 serves to ensure

that patents are granted on only those inventions that are "useful". *Manual of Patent Examining Procedure* Section 2107.01 (8th Edition, February 2003 Revision). Therefore, to satisfy the requirements of 35 U.S.C. Section 101, an applicant must claim an invention that is statutory subject matter and must show that the claimed invention is "useful" for some purpose, either explicitly or implicitly. *Id.*

To be "useful" for some purpose, the invention must have a specific and substantial utility (i.e. "a practical utility"). A "specific" utility is specific to the subject matter claimed (versus a "general utility" that would be applicable to a broad class of invention). A "substantial utility" defines a "real world" use. Not only must the invention have a specific and substantial utility, but also this utility must be credible. Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g. test data, affidavits or declarations from experts in the art, patents or printed publications). *Manual of Patent Examining Procedure* Section 2107 (8th Edition, February 2003 Revision). An applicant need only provide one credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement. *Id.*

Rejections under 35 U.S.C. Section 101 have been rarely sustained by the federal courts. *Manual of Patent Examining Procedure* Section 2107.02 (8th Edition, February 2003 Revision). Generally speaking, in these rare cases, the 35 U.S.C. Section 101 rejection was sustained either because the applicant failed to disclose any utility for the invention or the asserted utility could only be true if it violated a scientific principle, such as the second law of thermodynamics, or a law of nature or was wholly inconsistent with contemporary knowledge in the art. *Id.* (emphasis added).

Clearly, the Examiner has not questioned whether the claimed invention is eligible subject matter for patent protection under 35 U.S.C. Section 101. Instead, the Examiner has rejected claims 17-19 under 35 U.S.C. Section 101 as lacking a specific asserted utility or a well-established utility.

The Examiner mentions the credibility requirement of related subject matter such as gene therapy in the Office Action. Applicants respectfully would like to direct the Examiner to the Utility Examination Guidelines, Federal Register, Vol. 66, No. 4, pages 1092-1099, January, 2001. Applicants have studied the Guidelines and submit that the claims fully meet the utility standard as promulgated by the Guidelines.

On page 1092, the Guidelines state that with respect to genes, an inventor can patent a discovery when the patent application satisfies the statutory requirements. On page 1093, it is stated that an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it. When the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the "utility" requirement. That is, where the application discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable. *Id.* Applicants submit that based on the information in the specification and stated above, there is at least one specific and substantial utility that is credible.

On page 1093, it is also stated that synthetic DNA preparations are eligible for patents because their purified state is different from the natural occurring compound. On page 1094, it is stated that it is a long tradition in the United States that discoveries from nature which are transformed into new and useful products are eligible for patents (emphasis added). The patentee is required to disclose only one utility, that is, teach others how to use the invention at least one way (emphasis added). The patentee is not required to disclose all possible uses, but promoting the subsequent discovery of other uses is one of the benefits of the patent system. "When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. The USPTO is not authorized to withhold the patent

until another, or better, use is discovered." Other researchers may discover higher, better or more practical uses, but they are advantaged by the starting point that the original disclosure provides." *Id.* "An isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene." *Id.* Applicants have shown above that the claimed polypeptides can be used to produce a useful protein that serves as a marker for the disease of the prostate.

On page 1095, it is stated that if a well-established utility is readily apparent, the disclosure is deemed to be implicit. As discussed by Applicants above, the use of synthetic proteins to determine the antigen-protein complexes via epitopes is highly relevant and is a well-established benefit in the art. Finally, on page 1096, it is stated that a patent examiner must accept a utility asserted by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. "A rigorous correlation need not be shown in order to establish practical utility: reasonable correlation is sufficient." *Id.*

Thus, Applicants respectfully submit that the Examiner's rejection of the claimed polypeptide as having no utility is flawed. The polypeptides are derived from a gene that may not be found as individual parts of a gene in the cell naturally. However, they are useful in producing or recognizing peptides which contain epitopes which are relevant for protein complexes and finding antibodies, and ultimately other markers specific for prostate tissue diseases. A novel nut that may not be so significant by itself, but is significant in the functioning of a machine which performs a larger task, would still considered to have a specific utility under the realm of 35 U.S.C. § 101.

In order to expedite prosecution, Applicants have deleted the "at least 50% identity" language as well as the "PS118" language. For these reason, Applicants respectfully request withdrawal of the rejection of claims 17-19 under 35 U.S.C. § 101.

Rejection of Claims 17-19 Under 35 U.S.C. § 112, First Paragraph

Claims 17-19 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Specifically, the Examiner states that since SEQ ID NOS: 27-31 are derived from PS118, Applicants' failure to define PS118 in the specification and failure to relate any known structure from the polypeptides render the claims rejectable under 35 U.S.C. § 112, first paragraph. The Examiner further states that the claimed variants having 50% identity is insufficiently supported by the specification since there are no disclosure of any specific structure. Applicants respectfully traverse the rejection.

As noted above, the claimed polypeptides contain epitopes that are relevant to the binding of substrates and therefore useful as markers for other molecules. Such features are not describable in terms in words. On page 17, lines 5-11, it is disclosed the significance of an epitope, which is defined as an antigenic determinant of a polypeptide or protein, and the method of determining such is by spatial confirmation (x-ray crystallography or two dimensional nuclear magnetic resonance) which are known to those of ordinary skill in the art.
As stated above, the sequence of a polynucleotide is relevant with respect to structure as well as function since they carry information relating to epitopes. As indicated in the specification, the epitopes are relevant and distinguished in a number of ways, such as x-ray crystallography or two-dimensional magnetic resonance, all of which are not easily describable by words. Thus, the significance of the structure of the polynucleotides are described via their SEQ ID NO as allowed in the Eli Lilly cases discussed in the Guidelines.

The Examiner's arguments on page 14 reiterate arguments above and Applicants' responses above are incorporated herein. Applicants submit that the disclosure of conservative and non-conservative substitution and other structural features are not strictly required as indicated above and in the Guidelines.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 17-19 under 35 U.S.C. § 112, first paragraph.

Rejection of Claims 17-19 Under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 17-19 are rejected under 35 U.S.C. § 112, first paragraph, for not being supported by specific, substantial utility or a well established utility such that one skilled in the art would not know how to use the claimed invention. The Examiner does not state any specifics except pointing out the rejection under 35 U.S.C. § 101 above.

Therefore, Applicants' arguments above are incorporated herein.
For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-19 under 35 U.S.C. § 112, first paragraph, enablement.

Rejection of Claims 17-19 Under 35 U.S.C. § 112, First Paragraph, Scope of Enablement

Claims 17-19 are rejected under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope of these claims. The Examiner states that, while the specification is enabling for the polypeptide of SEQ ID NO: 27, it does not reasonably provide enablement for polypeptide "variants" of the polypeptide of SEQ ID NO: 27. The Examiner further alleges that Applicants have not shown how to make and use the claimed polypeptide variants which are capable of functioning as that which is being disclosed. Similar with the Examiner's arguments regarding the unpredictability of gene therapy, as reiterated and addressed above by Applicants, the Examiner states that protein chemistry is one of the most unpredictable areas of biotechnology. The Examiner concludes that in view of the unpredictability, one of ordinary skill in the art would be forced to perform undue experimentation in order to perform the claimed invention as broadly claimed.

These arguments have been addressed above and Applicants' arguments are incorporated herein. Briefly, the claims are drawn to specific sequences of amino acids as recited, SEQ ID NOS: 27-31. These sequences contain important epitopes as explained above. The Examiner's arguments regarding the unpredictability of an area of science does not preclude a demonstrated statutory utility as discussed above. With respect to the issue of undue experimentation, as stated above, the Guidelines specifically states that a rigorous correlation need not be shown in order to establish practical utility: "reasonable correlation is sufficient, that the USPTO is not authorized to withhold a patent until another, or better, use is discovered, and that promoting the subsequent discovery of other uses is one of the benefits of the patent system." *Id.* Applicants reiterate that the claims are drawn to a product instead of a specific method of use. In order to expedite prosecution, Applicants have amended the claims to delete the percent identity requirements and language pertaining to fragments of the claimed sequences.

For these reasons, Applicants respectfully request withdrawal of the rejection of claims 17-19 under 35 U.S.C. § 112, first paragraph, scope of enablement.

Rejection of Claims 17-19 Under 35 U.S.C. § 102(b)

Claims 17-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Girdham, CG *et al.*,1991 (herein Girdham), or Bork, P. *et al.*, 1993, Gen Bank Accession No: P34739, National Center for Biotechnology Information, National Library of Medicine, Bethesda, Maryland (herein Bork).

Specifically, the Examiner states that the claim language contains the "fragments" and "50% percent identity" phrases. The Examiner further states that there is no definition of PS118 in the specification. Applicants have deleted the "fragments" and "50% percent identity" phrases from the claim language. The definition of PS118 in the specification is not required as addressed above by Applicants. Applicants' arguments are incorporated herein.

The Examiner's prior art rejection is confusing. The Examiner states "US 6140468 prostate specific antigen produced by recombinant technique." It appears that this is a typographical error, since 1) it appears that the Examiner is referring to a U.S. patent, although that reference is not clearly incorporated in the prior art rejection, and 2) it appears that if this reference is applied, it is applicable, if at all, under a 35 U.S.C. § 103 prior art rejection, but the Examiner has not rejected any of the claims under this statute. If this reference is applied in a prior art rejection, Applicants request an explanation as required under the M.P.E.P.

The Examiner's prior art rejection is further confusing because the claims are rejected under 35 U.S.C. § 102(b) instead of 35 U.S.C. § 103, but the Examiner states that the claimed fragments appears to be the same as the prior art fragments, and that "The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product." Applicants submit that the claims now recite specific polypeptide sequences, SEQ ID NOS: 27-31 and that the claims do not recite any structural and functional characteristics of the claimed product as alleged by the Examiner.

The Examiner has not pointed out any sequences from the prior art in order for Applicants to respond to the Examiner's prior art rejection properly, as required by the M.P.E.P. There are no disclosed sequences from Girham, Bork nor U.S. Patent No. 6,140,468 matching SEQ ID NOS: 27-31. The Examiner's citation to "Girham, CG *et al.*, 1991" is incomplete, as this citation merely points out the authors' names and year of publication. The Examiner has not provided a copy of the reference such that it is impossible for Applicants to determine what article the Examiner is referring in her basis for the rejection. The Examiner further cites Accession No: P34739 without providing a copy of the disclosure to Applicants. Applicants have attempted to look for this accession number but it appears that the Accession No: P34739 does not exist. With respect to U.S. Patent No. 6,140,468 to Vikho, Applicants submit that Vikho merely discloses the

production and purification of the human PSA. Vikho only discloses one very short sequence, SEQ ID NO: 1 consisting of thirteen amino acids. Vikho does not disclose any sequences selected from the group consisting of Applicants' SEQ ID NOS: 27-31.

The Examiner's prior art rejection is confusing such that Applicants cannot respond in a meaningful manner. Applicants respectfully request that if the prior art rejection using Girham, Bork or U.S. Patent No. 6,140,468 is maintained, the Examiner should issue a non-final Office Action with further explanations so that Applicants can respond.

Accordingly, Applicants respectfully request withdrawal of the rejection of claims 17-19 under 35 U.S.C. § 102(b).

CONCLUSION

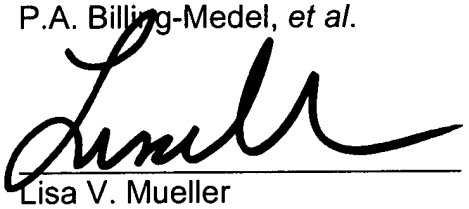
Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. Sections 101, 112, 102 and 103. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below. If the Examiner notes any further matters which the Examiner believes may be expedited by a telephone interview, the Examiner is requested to contact the undersigned.

If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge deposit account no. 23-0785.

Respectfully submitted,

P.A. Billing-Medel, *et al.*



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